

- a metal ion-binding domain which comprises the sequence Gly-Gly-Z or Gly-Gly-Gly-Z wherein Z is selected from the group consisting of cysteine, homocysteine, isocysteine, penicillamine, 2-mercaptoethylamine, 3-mercaptopropylamine and D-stereoisomers thereof,
- said peptide bearing a Tc-99m ion which has been coupled to said metal ion-binding domain; and
- (b) detecting the Tc-99m bearing peptide, and thereby determining the existence and locus of infection or inflammation.--
- b1
Concl

REMARKS

Cancellation of Rejected Claims

The foregoing Amendment cancels claims 25 through 33 which have been rejected under the first paragraph of 35 U.S.C. § 112 on the ground that they are not supported by the disclosure of the original specification. The Examiner also held that, even if said claims are found to have support in the specification, they would be subject to restriction as independent or distinct from the invention being prosecuted in this application.

Proposed Interference

By this Amendment, Applicants are presenting claims 34 through 37 and respectfully request that an interference be declared between the above application and U.S. Patent No. 5,670,133. The information required by 37 C.F.R. § 1.607(a) is

set forth under headings which correspond to the relevant subsections of 37 C.F.R. § 1.607(a).

(1) Identification of the Interfering Patent: The patent which claims subject matter interfering with the subject matter claimed in the instant application is U.S. Patent No. 5,670,133 issued to Paul O. Zamora and entitled "Peptides[,] Method for Radiolabeling Them, and Method for Detecting Inflammation". The Zamora patent was issued on application No. 08/484,184 filed on 7 June 1995 which purports on its face to be a continuation of application No. 08/087,219 filed on 2 July 1993, which in turn purports to be a continuation-in-part of application No. 07/840,077 filed on 20 February 1992 (now U.S. Patent No. 5,443,816). Rhomed Incorporated of Albuquerque, New Mexico, is the assignee named on the face of the patent.

Application No. 08/087,219 has now issued as U.S. Patent No. 5,700,444. Copies of U.S. Patents Nos. 5,443,816, 5,670,133 and 5,700,444 are here attached.

Applicants acknowledge that patentee Zamora would, in an interference involving his U.S. Patent No. 5,670,133 (hereinafter "the '133 Patent") be entitled to the benefit of the filing date of application No. 08/087,219 (hereinafter "the '444 Patent"). It is submitted, however, that, in such interference, he would not be entitled to the benefit of the filing date of application No. 07/840,077 (hereinafter "the '816 Patent").

The '444 Patent purports on its face to be a continuation-in-part of the '816 Patent and there is a Terminal

Disclaimer so that both of these patents will expire on the same day. Whether or not the claims of the '444 Patent are, in fact, supported in the disclosure of the '816 Patent is of no relevance for present purposes and Applicants express no opinion on this issue. Applicants assert, however, that the claims of the '133 Patent are not supported in the disclosure of the '816 Patent.¹

The '133 Patent is concerned with peptides comprising a biological-function domain and a metal ion-binding domain which includes the amino acid sequences Gly-Gly-Cys, Gly-Gly-Pen, Gly-Gly-Gly-Cys or Gly-Gly-Gly-Pen. These sequences are not disclosed in the '816 Patent. The amino acid sequences for the metal ion-binding domain are set forth in the generic formulae and definitions at column 5, lines 30-42; the structural formulae do not include the aforementioned sequences. And even considering the definition of "R₂" as including part of the biological function domain, none of the specifically mentioned biological function domains -- at column 5, line 66 through column 6, line 29, and in the sequence listings -- show any of the sequences Gly-Gly-Cys, Gly-Gly-Pen, Gly-Gly-Gly-Cys or Gly-Gly-Gly-Pen. Therefore, since these sequences are not disclosed in the '816 Patent as either part of the biological-function domain or part of the metal ion-binding domain, the claims of the

¹ Applicants appreciate the fact that the comparison should be made between the claims of the '133 Patent and the text of application No. 07/840,077 as originally filed. However, there is no substantial difference between the disclosure of the originally-filed application and the specification in the '816 Patent and it is believed to be more convenient to refer to the '816 Patent.

'133 Patent are not entitled to the benefit of the filing date of the '816 Patent.

(2) Proposed Count: Applicants propose a single count reading:

A peptide comprising

a biological-function domain which causes the peptide to localize at a target site, and

a metal ion-binding domain which comprises the sequence Gly-Gly-Z or Gly-Gly-Gly-Z wherein Z is selected from the group consisting of cysteine, homocysteine, isocysteine, penicillamine, 2-mercaptoethylamine, 3-mercaptopropylamine and D-stereoisomers thereof.

The proposed count is a phantom count prepared in accordance with MPEP § 2309 (6th ed., Jan. 1995) in order to encompass the broadest patentable interfering subject matter common to both parties.

The term "peptide" is to be understood as including -- in addition to the usual amino acids -- modifications, deletions, substitutions, cyclations or "amino acid mimics" as set forth in the '133 Patent at column 6, lines 4-10. Thus, the presence of 2-mercaptoethylamine and 3-mercaptopropylamine is appropriate in the proposed count.

(3) The Claims in U.S. Patent No. 5,670,133 which Correspond to the Proposed Count. All of the claims in the '133 Patent correspond to the proposed count.

Claim 1 and the proposed count are directed to a peptide comprising a biological function domain and a metal ion-binding domain. The attached Appendix A is a side-by-side comparison of the terms of claim 1 and the proposed count. Claims 2 through 7 are dependent on claim 1.

Claim 8 covers a method of labelling a peptide with a metal ion. Claim 14 covers a method for radiolabelling a peptide. Claim 20 covers a method of detecting the existence or locus of infection or inflammation in the body of a mammalian subject said method involving the use of a labelled peptide. The peptides recited in claims 8, 14 and 20 are substantially identical to the peptides claimed in claim 1. Claims 9 through 13 are dependent on claim 8. Claims 16 through 19 are dependent on claim 14. Claims 20 and 21 are dependent on claim 20.

(4) Identification of the Claims in Application No. 08/236,402 which Correspond to the Proposed Count: Newly presented claims 34 through 37 correspond to the proposed count and were, to the extent possible, "copied" from the '133 Patent.

In the Office Action of 3 March 1998, the Examiner ruled that claims 1-3, 5, 6, 10, 18-21 and 24 are in condition for allowance. Claims 7, 8, 11-17, 22 and 23 have been withdrawn from consideration. Applicants' claims 1-3, 5-8 and 10-24 cover subject matter included in claims 34-37.

Claim 34 corresponds exactly to the proposed count.

Claim 35 is analogous to claim 4 of the '133 Patent. Claim 35 is dependent on Applicants' claim 34, which corresponds exactly to the proposed count. Applicants' claims 7, 8, 11-14, 22 and 23 are analogous in part to claim 4 of the '133 patent.

Claim 36 is analogous to claim 8 of the '133 Patent. In claim 36, the metal ion used for radiolabelling is limited to technetium-99m. The peptide recited is identical to the peptide claimed in claim 34, which corresponds exactly to the count. Applicants' claims 15 and 16 are analogous in part to claim 8 of the '133 patent.

Claim 37 is analogous to claim 20 of the '133 Patent. Again, the metal ion used for labelling has been limited to technetium-99m and the cited peptide is identical to the peptide claimed in claim 34, which corresponds exactly to the count. Applicants' claim 17 is analogous in part to claim 20 of the '133 patent.

Claim 1 is directed to a "reagent for preparing a scintigraphic imaging agent", and this term is analogous to the "peptide" which is the subject matter of the count. The attached Exhibit B is a side-by-side comparison of the language of claim 1 and of the proposed count. As can be seen, the terms of claim 1 are either synonymous with or inclusive of the terms of the proposed count. The "radiolabel complexing moiety" of claim 1 corresponds to the "metal ion-binding domain" of the proposed count but Applicants' moiety includes amino acids which are not

encompassed in the domain of the count. Claims 2, 3, 5, 6, 10, 18-21 and 24 are, along with claim 1, in condition for allowance.

(5) Application of the Terms of Applicants' Newly Presented Claims to Applicants' Disclosure. In the proposed interference, Applicants will be entitled to the benefit of application No. 07/807,062 filed on 27 November 1991, now U.S. Patent No. 5,443,815 (hereinafter "the '815 Patent"), copy of which is here attached. In order to show clearly that Applicants are entitled to this filing date, the terms of the newly presented claims are also being applied to the disclosure of the '815 Patent.² The attached Appendix C applies the terms of the claims to the disclosure of application No. 08/236,402. The attached Appendix D applies the terms of the claims to the disclosure of the '815 Patent.

The Requirement for Restriction

In the Office Action herein responded to, the Examiner has reiterated a requirement for restriction which she had previously made. In view of the foregoing Amendment, the requirement for restriction is understood to be as follows³:

² Applicants appreciate the fact that the comparison should be made between their newly presented claims and the text of application No. 07/807,062 as originally filed. However, there is no substantial difference between the disclosure of the originally-filed application and the specification in the '815 Patent and it is believed to be more convenient to refer to the '815 Patent.

³ The Office Action omitted a Group II. What probably should have been Group V was indicated as Group VI; the claims in this Group have been cancelled.

- I. Claims 1-3, 5, 6, 10, 18-21 and 24
- II. Claims 7, 8, 11-14, 22 and 23
- III. Claims 15 and 16
- IV. Claim 17

It is again respectfully requested that this requirement for restriction be reconsidered.

Reconsideration of the restriction requirement is requested in view of Applicants' submission under 37 C.F.R. § 1.607 for the purposes of provoking interference with the '133 Patent. Each of the foregoing groups of claims has its counterpart in the issued claims of the '133 Patent, namely:

Group I -- claims 1 and 3 of the '133 Patent

Group II -- claims 2 and 4-7 of the '133 Patent

Group III -- claims 8-19 of the '133 Patent

Group IV -- claims 20-23 of the '133 Patent

As pointed out above, all of the claims of the '133 Patent correspond to the proposed count and, likewise, all of the claims in the instant application would correspond to the proposed count. It would, of course, be possible for Applicants to cancel the claims which the Examiner deems to be non-elected in the instant application, to file three divisional applications and then to attempt to provoke one or more additional interferences with the '133 Patent (or, in the alternative, to attempt to add these new applications to an interference between the allowed claims of the instant application and the '133 Patent). Applicants submit, however, that to follow this procedure would cause unnecessary delay. The Examiner's attention is

respectfully directed to 37 C.F.R. § 1.601 which states, in pertinent part:

This subpart shall be construed to secure that just, speedy and inexpensive determination of every interference.

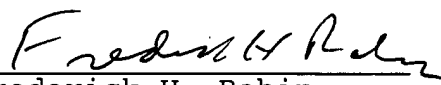
This goal is best attained by the Examiner formally examining the non-elected claims in the instant application. Since all of these claims involve Applicants' claimed reagent for preparing a scintigraphic imaging agent, it is believed that no substantial additional effort on the part of the Examiner will be required.

Conclusion

Accompanying this submission is a Statement under 37 C.F.R. § 1.608(a). It is requested that an interference be declared with the '133 Patent and that Applicants be designated as senior party.

Respectfully submitted,

Date: 14 April 98


Frederick H. Rabin
Reg. No. 24,488

Fish & Richardson P.C.
45 Rockefeller Plaza
New York, NY 10111

Telephone: 212/765-5070
Facsimile: 212/258-2291

Enclosures: Appendices A, B, C, D
 Statement under 37 C.F.R. § 1.608(a)
 U.S. Patent Nos. 5,443,815; 5,443,816; 5,670,133
 and 5,700,444

33889.N11